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APPLICATION NO. 324	FILING DATE 05/24/94	FIRST NAMED INVENTOR OSBORN	ATTORNEY DOCKET NO. 163363
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EXAMINER WOITACH, J

ART UNIT 1632	PAPER NUMBER
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DATE MAILED:

05/23/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/217,324	Applicant(s) OSBORNE ET AL.	
	Examiner Joseph T. Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2001 (paper number 31) has been entered.

This application is an original application filed March 24, 1994.

Applicant's amendment filed March 12, 2001, paper number 32 has been received and entered. Claims 1, 10, 11, 13-16 and 19-22 have been amended. Claims 1-22 are pending and currently under examination.

Response to Amendment

The Declaration of William R. A. Osborne submitted under 37 CFR 1.132 filed March 12, 2001, paper number 29, is sufficient to overcome the 35 USC 103 rejection of claims 1-22 based upon Zalewski *et al.* Nabel *et al.* and Anderson *et al.*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-22 stand rejected and claims 12-22 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that the invention departs from normal gene therapy protocols and that practice of the claimed invention in light of the *in vitro* and *in vivo* examples demonstrate that the specification provides adequate guidance to overcome the areas pointed out as highly unpredictable in the previous office actions. See Applicants amendment page 5. Applicants arguments have been fully considered but not found persuasive.

In order to advance prosecution Applicants have amended claims 11-22 to encompass only a method of preparing a device for implanting autologous vascular smooth muscle cells transduced with a gene of interest. The claims no longer encompass a method of introducing a gene of interest into a mammalian subject, however the pending claims are all directed to use of the device for implanting (claim 1) or for preparing a vascular prosthesis (claim 11) each which is directed to use *in vivo*. It is noted that as set forth previously during the prosecution of the instant application, that the instant claimed device has use *in vitro*, however none of the claims are restricted to this use and all the pending claims recite and encompass use *in vivo*. Further, in light

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of the specification, the only intended use set forth for the device is for delivery to subject for *ex vivo* for gene therapy. The rejection of record set forth in the previous office action (paper number 19) as applied to the methods of introducing and expressing a gene of interest are maintained as they apply to a method of making a device for implantation, because the methods must provide the necessary guidance to fully enable the product that is produced. The rejection is also applied to claims 1-11 which is a product claim drawn to the device for implantation.

Examiner would agree that the specification provides adequate guidance for the creation of an explant culturing device, however the claims are drawn specifically to a device for implantation and thus, encompass the intended use for the *in vivo* delivery of a gene of interest, and must be fully enabled for this use.

Therefore, for the reasons above and of record, in view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art at the time of the claimed invention was made, it would have required on of skill in the art undue experimentation to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 2-10 and 12-19 are unclear in the recitation of 'A device as in claim' and 'A method as in claim' because the antecedent basis of the device and the method is not clearly defined. The specification teaches variations on devices for implantation and methods of preparing said devices, and in light of the specification it is unclear if the claims also encompass these variations or only the device or method as recited in the independent claim. Amending the claims to recite --The device/method of claim-- would obviate the basis of this rejection.

Claim 11 is unclear because the preamble recites preparing a vascular prosthesis, however the method steps only encompass preparing a vascular graft device which may or may not be appropriate for use as a vascular prosthesis. Further, the claim is incomplete because the method steps do not result in the producing the claimed product of a vascular prosthesis.

Claim 15 is unclear in the recitation of 'the gene encodes granulocyte colony stimulating factor, granulocyte macrophage colony stimulating factor' because it is unclear if the gene encodes both of these factors together or only one of these factors selected from the group consisting of granulocyte colony stimulating factor and granulocyte macrophage colony stimulating factor or similar to the recitation in claim 6.

Claim 19 is unclear in the recitation of 'glucose-regulated insulin or proinsulin polypeptide' because it is unclear if the regulation of expression of the gene of interest, in this

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case insulin or proinsulin, is in response to glucose, or if the claim simply refers to the insulin and proinsulin polypeptides. In light of the specification and the art, it is unclear how 'glucose-regulated' is meant to modify or distinguish insulin and proinsulin encompassed in the claim. Deleting [glucose-regulated] would obviate the basis of this rejection. In addition, the recitation of 'encoded' in line 2 should be amended to --encodes-- for verb clarity.

Claim 20 is unclear in the recitation of 'the graft' in line 8 because the antecedent basis is not clearly defined in the preamble or preceding portion of the claim. Amending the claim to recite the graft --device-- as in line 9 would obviate the basis of the rejection. In addition, the claim is unclear because the preamble recites preparing a vascular prosthesis, however the method steps only encompass preparing a vascular graft device which may or may not be appropriate for use as a vascular prosthesis.

Claims 21 is unclear in the recitation of 'cultivating the vascular endothelial cells obtained from a mammal' because cultivating is not clearly defined in the specification and it is unclear what is encompassed by this term with respect to tissue culture cells. Amending the claim to recite culturing would obviate the basis of this rejection. In addition, the antecedent basis for 'the vascular endothelial cells obtained from a mammalian subject' is not clear because claim 20 does not recite from where or how the cells in line 4 were isolated, and the antecedent basis for 'the vascular graft' in line 3 is not clear because claim 20 recites only 'a vascular prosthesis' and does not recite a 'graft'.

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Claim 22 is unclear in the recitation of 'cultivating the vascular smooth muscle cells obtained from a mammal' because it is not clearly defined in the specification and it is unclear what is encompassed by this term with respect to tissue culture cells. Amending the claim to recite culturing would obviate the basis of this rejection. In addition, the antecedent basis for the vascular smooth muscle cells is not clear because claim 20 does not recite from where or how the cells in line 4 were isolated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4, 6, 11, 12 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Osborne *et al.*

Claims 1, 2 and 4 are drawn to a device for implanting autologous vascular smooth muscle cells which express a gene of interest in a tubular elongate member having a pores wall. Claim 6 is drawn to a device wherein the gene of interest is granulocyte colony stimulating factor or granulocyte macrophage colony stimulating factor. Claims 11, 12 and 15 are drawn to a method of making said devices. Osborne *et al.* teach smooth muscle cells transfected and seeded *ex vivo*

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onto Gortex vessels to provide arterial implants. One gene of interest which is expressed by the smooth muscles cells is granulocyte colony stimulating factor. Osborne *et al.* teach to transfect the smooth muscle cells then transplant them onto the Gortex therefore they teach the necessary method steps which anticipate the method claims. Thus, Osborne *et al.* anticipate the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M. Hauda, can be reached at (703)305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Kay Pickney whose telephone number is (703)306-3076.

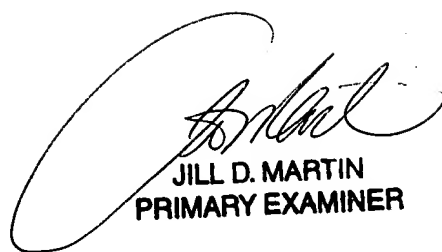
Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

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Joseph T. Voitach



JILL D. MARTIN
PRIMARY EXAMINER